Near Patient Testing: *H. pylori*

CAMBRIDGE Life Sciences

Endosc-Hp® TEST

KEY POINTS:

- **Accurate - specifically designed to detect the urease enzyme of *Helicobacter pylori***
- **Flexible - twin wells allow two specimens per patient, second well can be used as a control**
- **Practical - room temperature storage**
- **No wasted reagents - once reconstituted the solution is stable for 5 days at 18-25°C**
- **Quick - result usually within 30 minutes, any colour change from yellow through orange to magenta indicates a positive reaction**

INDICATION:

The Endosc-*Hp*® test detects the urease enzyme of *Helicobacter pylori* present in gastric mucosal biopsies.

BACKGROUND:

Helicobacter pylori is a bacterium that is found in the gastric mucous layer or adherent to the epithelial lining of the stomach. Helicobacter pylori causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers.*
Most persons who are infected with Helicobacter pylori never suffer any symptoms related to the infection; however, Helicobacter pylori causes chronic active, chronic persistent, and atrophic gastritis in adults and children.
Since it is known that most ulcers are caused by Helicobacter pylori, appropriate antibiotic regimens can successfully eradicate the infection in most patients, with complete resolution of the mucosal inflammation and a minimal chance for recurrence of ulcers.

***Source: CDC Centers for Disease Control and Prevention, Fact Sheet for Health Care Providers "Helicobacter pylori" Updated July 1998**

SUMMARY AND EXPLANATION OF TEST:

The Endosc-*Hp*® test consists of a twin well cartridge containing urea, phenol red and buffer salts in a tablet form and an ampoule of buffer. If the urease enzyme of *Helicobacter pylori* is present in a biopsy specimen, the rise in pH associated with the hydrolysis of urea causes a change in colour from yellow through orange to magenta.

ORDERING INFORMATION	CONFIGURATION	PART NUMBER
ENDOSC-Hp® Test CE IVD 98/79/EC For in vitro diagnostic use and Professional Use only.	4 Tests consisting of a twin well cartridge containing a substrate tablet in each well. 4 ampoules of buffer	U1021

Cambridge Life Sciences Ltd.
14 St. Thomas' Place, Cambridgeshire Business Park, Ely, Cambs, CB7 4EX, UK
Telephone: +44 (0)1353 645200
E-mail: sales@clsdiagnostics.com
http://www.clsdiagnostics.com/

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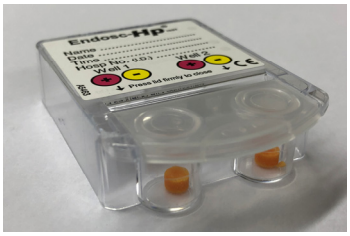

Remove Cartridge + Buffer from foil pouch

Fill each well to dissolve tablets

Add biospies to both wells or leave one well as negative control

Close lid, shake briefly. Positive result usually within 30 minutes

Stability and Quality Control:

The Endosc-*Hp*® test does not require cold storage. The Endosc-*Hp*® test has been designed for storage between 10°C and 28°C. After reconstituting the tablet, the solution is stable for 5 days at room temperature. If the test was reconstituted and not used, there is no wastage.

Shelf life is 24 months from date of manufacture. Expiry date is printed on the packaging.

The test also has an in-built quality control, if the solution becomes pink before the specimen is added the test should not be used.

Evaluation:

In 1998, a study, established in the Gastroenterology Unit of Leeds General Infirmary under the guidance of Dr Paul Moayyedi, Consultant Physician and Ms Berenice Quinlan, staff Nurse in the Dyspepsia Clinic, compared the performance of the Endosc-*Hp*® test with CLOtest™ and Histology.

To receive a copy of this study, please contact us at info@clsdiagnostics.com

Correlation:

100 patients were tested using the Endosc-*Hp*® test and CLOtest™ and all except 5 samples were also tested for histology (Geimsa stain).**
46 patients were female and 54 were male with an age range of 78 to 22 years. The tests were performed according to the manufacturer's instructions. Three biopsies were taken for the Endosc-*Hp*® test, CLOtest™ and for histology from the antrum. No record was taken whether these patients were on antibiotics, triple therapy or bismuth or whether they had been within the 3 weeks prior to the endoscopy.

**Source: Endosc-Hp® test Evaluation study by the Gastroenterology Unit from Leeds General Infirmary, 1998.

	Endosc-*Hp*® Test		
CLOtest™	Positive	Negative	Total
Positive	34	2	**36**
Negative	1	63	**64**
Total	**35**	**65**	**100**

Sensitivity:	94.4%
Specificity:	98.4%
Positive Predictive Value:	97.1%
Negative Predictive Value:	96.9%
Efficiency:	97.0%